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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,754	02/08/2001	Jeffrey E. Stahmann	279.380US1	5548
21186	7590	06/17/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,754

Applicant(s)

STAHMANN ET AL.

Examiner

Anu Ramana

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 71-75 is/are allowed.
- 6) ☒ Claim(s) 41, 42, 47-50, 55-61, 63, 66, 67, 69 and 70 is/are rejected.
- 7) ☒ Claim(s) 43-46, 51-54, 62, 64, 65 and 68 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/4/04
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 48, 49, 63 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Verboven-Nelissen (US 5,720,768).

Regarding claims 48, 49, 63 and 66, Verboven-Nelissen discloses an apparatus and method for pacing and sensing different chambers of a heart wherein a first electrode 159 is placed in the left ventricle, a second electrode 156 is placed in the right ventricle and a pacing and sensing vector is programmed between the two electrodes by an implantable pulse generator 10 (Fig. 2 and col. 5, lines 14-45).

The method steps of claims 48, 49, 63 and 66 are inherently performed during normal use of the Verboven-Nelissen apparatus for the purpose of pacing a heart.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 55, 56, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schloss (US 6,539,260) in view of Scheiner et al. (US 6,584,362).

Schloss discloses bipolar pacing between a tip electrode 130 disposed within a ventricle at an apex of the ventricle and a defibrillation electrode 150 within the ventricle at a location more proximal than tip electrode 130 (Figure 2, col. 7, lines 43-57).

Schloss does not disclose that first electrode 130 is an anode and second electrode 150 is a cathode.

Scheiner et al. teach a bipolar pacing lead in which the tip or ring electrode can be a cathode or anode depending on different thresholds (Fig. 7 and col. 8, lines 23-38).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed pacing between a tip electrode 130 acting as an anode and a defibrillation electrode 150 acting as a cathode, as taught by Scheiner et al. for providing different thresholds.

Claims 50 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verboven-Nelissen.

Regarding claims 50 and 67, Verboven-Nelissen discloses that sensing and pacing could occur between a first left ventricular electrode 159 and a conductive housing 134 of implantable generator 10 (col. 5, lines 23-59).

Verboven-Nelissen does not disclose switching from bipolar pacing (first pacing pulse between a left ventricular electrode and a right ventricular electrode) to unipolar pacing (second pacing pulse between a left ventricular electrode and the conductive housing of the implantable generator).

Switching from bipolar pacing to unipolar pacing and vice versa is well known as evidenced by Barreras et al. (US 4,558,702).

Accordingly it would have been obvious to one of ordinary skill in the art to have provided a first pacing pulse between a left ventricular electrode and a right ventricular electrode and a second pacing pulse between the a left ventricular electrode and the conductive housing of the Verboven-Nelissen apparatus, to switch from a bipolar pacing mode to a unipolar pacing mode.

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Claims 41, 42, 47 and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schloss.

Schloss discloses an implantable medical device with an implantable ventricular lead 30 having a first electrode 32 in the right ventricular apex and an electrode 22 in the right atrial region wherein pacing and sensing are performed between the right ventricular electrode and the right atrial electrode (Figure 1 and col. 4, lines 17-35).

Schloss further discloses that the housing 40 of the stimulation device ("case electrode") can be programmed to act in combination with the first and second electrodes (col. 4, lines 52-67).

Although Schloss does not disclose a left ventricular electrode, Schloss discloses that additional stimulation leads with one or more pacing/sensing electrodes may be used in order to efficiently and effectively provide pacing stimulation to the left side of the heart (col. 4, lines 36-45).

Applicant does not disclose the criticality of pacing between an electrode in the right atrium and an electrode in the left ventricle.

Accordingly performing pacing between an electrode in the right atrium and an electrode in the left ventricle is deemed to be a design consideration and does not patentably distinguish over Schloss.

Regarding claims 47 and 58-60, Schloss teaches a large surface electrode to achieve capture (col. 8, lines 40-49). Further, it is well known to connect multiple electrodes in common to form a large surface electrode as evidenced by Ayers et al. (US 5,405,375).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided first and third left ventricular electrodes connected in common, to provide a large surface electrode to achieve capture.

The method steps of claims 41, 42, 47 and 57-61 are rendered obvious by the above discussion.

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Allowable Subject Matter

Claims 43-46, 51-54, 62, 64, 65 and 68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 71-75 are allowed.

Response to Arguments

Applicant's arguments with respect to rejection of claims 48, 49, 63 and 66 as being anticipated by Verboven-Nelissen (US 5,720,768 or '768 herein) have been considered but are not persuasive. '768 discloses pacing and sensing in Figure 2, blocks 130, 170 and 172.

Applicants' arguments with respect to claims 55, 56, 69 and 70 are moot in view of the new rejections made in this Office Action.

Applicants' arguments with respect to the rejections of claims 41, 42, 47 and 57-60 are not persuasive. It is noted that Applicants' arguments are directed to unclaimed subject matter and subject matter not found in the disclosure.

Applicants' arguments with respect to claims 43-46, 51-54, 62, 64, 65, 68 and 71-75 are persuasive. Accordingly the rejections of these claims have been withdrawn in this Office Action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Amudha Ramana*
June 14, 2004

Kevin Shaver
KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700